DISTRICT OF COLUMBIA MUNICIPAL REGULATIONS for RADIATION: SPECIFIC LICENSE PROCEDURES

May 5, 2006

CHAPTER 69. RADIATION: SPECIFIC LICENSE PROCEDURES

6900. APPLICATION FOR SPECIFIC LICENSES.

6900.1 Applications for specific licenses shall be filed with the Director on a form prescribed by the Director, and containing information that the Director may require.

6900.2 At any time after the filing of the original application, and before the expiration of the license, the Director may require further statements in order to determine whether the application should be granted or denied or whether a license should be modified or revoked.

6900.3 Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his or her behalf.

6900.4 In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Director;

Provided, that the references shall be clear and specific.

6900.5 An application may include a request for a license authorizing one (1) or more purposes.

6900.6 Applications and documents submitted to the Director may be made available for public inspection, except that the Director may withhold all or part of any document from public inspection if disclosure of its contents is not required in the public interest and would adversely affect the interest of a person concerned.

6901. GENERAL REQUIREMENTS FOR ISSUANCE OF LICENSES.

6901.1 A license application shall be approved if the Director determines that the requirements of this section have been satisfied.

6901.2 The applicant shall qualify by reason of training and experience to use the material in question for the purpose requested in accordance with these regulations in a manner that minimizes danger to public health, safety, and property.

6901.3 The applicant's proposed equipment, facilities, and procedures shall be adequate to minimize danger to public health, safety, and property.

6901.4 The issuance of the license shall not be inimical to the health and safety of the public.

6901.5 The applicant shall satisfy the applicable special requirements for each specific license requested pursuant to §§ 6910 through 6916 of this chapter.

6901.6 Upon a determination that an application meets the requirements of these regulations, the Director shall issue a specific license authorizing the proposed activity. The license shall state the conditions of and the limitations on the license as are deemed appropriate or necessary.

6901.7 The Director may incorporate in any license at the time of its issuance, or after it is issued by appropriate rule or order, any additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material, subject to the radiation provisions of this title, as are deemed appropriate or necessary in order to do the following:

(a) Minimize danger to public health and safety or property;

(b) Require any reports, the keeping of records and provide for inspections and activities under the license as may be appropriate or necessary; and

(c) Prevent loss or theft of material subject to the radiation provisions of this title.

6902. SPECIFIC TERMS AND CONDITIONS OF LICENSES.

6902.1 Each license issued pursuant to the radiation provisions of this title shall be subject to all rules, regulations, orders, and standards of the Department.

6902.2 Each person licensed by the Director pursuant to the radiation provisions of this title shall confine his or her use and possession of the material licensed to the locations and purposes authorized in the license.

6902.3 Each licensee authorized under § 6912 of this chapter to distribute certain devices to generally licensed persons shall report to the Director all transfers of the devices to persons generally licensed under § 6803 of chapter 68 of this title.

6902.4 The report required by § 6902.3 shall identify each general licensee by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device.

6902.5 The report required by § 6902.3 shall be submitted within thirty (30) days after the end of each calendar quarter in which a device is transferred to a generally licensed person.

6902.6 Each licensee authorized under § 6912 to distribute certain devices to generally licensed persons shall furnish to each general licensee in the District to whom he or she transfers a device a copy of the general license contained in § 6803 of chapter 68 of this title.

6902.7 No license issued or granted under the radiation provisions of this title, and no right to possess or utilize radioactive material granted by any license issued pursuant to those provisions, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, or through transfer of control of any license to any person unless the Director finds that the transfer is in accordance with the radiation provisions of this title and consents in writing to a transfer, assignment, or another means of disposal. The director shall base his or her finding on full information.

6903. RENEWAL AND AMENDMENT OF LICENSES.

6903.1 Each application for renewal of a specific license shall be filed in accordance with § 6900 of this chapter.

6903.2 In any case in which a licensee has filed an application not less than thirty (30) days prior to the expiration of his or her existing license, and has filed the application in proper form for renewal or for a new license authorizing the same activities, the existing license shall not expire until a decision on the application has been made by the Director.

6903.3 Each application for an amendment of a license shall be filed in accordance with § 6900 of this chapter, and shall specify the respects in which the licensee desires his or her

license to be amended and the grounds for the amendment.

6903.4 In considering an application by a licensee to renew or amend his or her license, the Director shall apply the criteria set forth in § 6901 and §§ 6910 through 6916 of this chapter as applicable.

6904. MODIFICATION, REVOCATION, AND TERMINATION OF LICENSES.

6904.1 The terms and conditions of all licenses shall be subject to amendment, revision, or modification, or the license may be suspended or revoked by reason of amendments to the radiation provisions of this title, or by requirements and orders issued by the Director.

6904.2 Any license may be revoked, suspended, or modified, in whole or in part, for any of the following reasons:

(a) Any material false statement in the application or any statement of fact required under the radiation provisions of this title;

(b) Because of conditions revealed by the application or statement of fact, or any report, record, or inspection or other means that would warrant the Director refusing to grant a license on an original application; or

(c) For violation of, or failure to observe, any of the terms and conditions of the license, or of the radiation provisions of this title, or order of the Director.

6904.3 Except in cases of willfulness, or in cases in which the public health, interest, or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings for the action, facts or conduct that may warrant the action have been called to the attention of the licensee in writing; and the licensee has been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

6904.4 The Director may terminate a specific license upon the written request of the licensee.

6905. TRANSFER OF RADIOACTIVE MATERIALS BY LICENSEES.

6905.1 No licensee shall transfer radioactive material except as authorized pursuant to this section.

6905.2 With the advance approval of the receiver, any licensee may transfer radioactive material to the following:

(a) The Department;

(b) The Nuclear Regulatory Commission (NRC);

(c) Any person exempt from the radiation provisions of this title to the extent permitted under the exemption; and

(d) Any person authorized to receive the material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Director, the NRC, or any agreement state, or to any person otherwise authorized to receive the material by the federal government or any federal government agency, the Director, or any agreement state.

6905.3 With advance approval of the receiver, a licensee may transfer radioactive material when authorized to do so by the Director in writing.

6906 - 6909. RESERVED.

6910. HUMAN USE OF RADIOACTIVE MATERIALS.

6910.1 A specific license for human use of radioactive material in institutions shall be issued only if the requirements of §§ 6910.2 through 6910.6 are satisfied.

6910.2 The applicant shall appoint and submit to the Director the names of the members of a medical radiation safety committee of at least three (3) members to evaluate all proposals for research, diagnostic, and therapeutic use of radioisotopes within that institution:

6910.3 Membership of the medical radiation safety committee required by § 6910.1 shall include physicians expert in internal medicine, hematology, and therapeutic radiology, and a person experienced in testing of radioisotopes and protection against radiation.

6910.4 The applicant shall possess adequate facilities for the clinical care of patients.

6910.5 The physician designated on the application as the individual user shall have substantial experience in the handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients.

6910.6 If the application is for the license to use unspecified quantities or multiple types of radioactive material, the applicant's staff shall have substantial experience in the use of radioactive materials for a variety of human uses.

6910.7 A specific license for the human use of radioactive materials shall be issued to an individual physician only if the applicant satisfies the following requirements:

(a) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and

(b) The applicant has extensive experience in the handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients.

6910.8 A specific license for human use of sealed sources shall be issued only if the applicant or, if the application is made by an institution, the individual user meets the following requirements:

(a) He or she has specialized training in the therapeutic use of the sealed source considered (such as a teletherapy unit, beta applicator, or similar device), or has experience equivalent to that training; and

(b) He or she is a physician.

6910.9 An application for a specific license pursuant to §§ 6910.1 through 6910.7 of this section for any diagnostic use of radioactive material in humans as specified in standards issued by the Director shall be approved for all of the diagnostic uses within the standards if the applicant satisfies the following requirements:

(a) The applicant satisfies the requirements of §§ 6910.1 through 6910.7;

(b) The applicant or the physician designated in the application as the individual user has adequate clinical experience in the performance of diagnostic procedures specified in the appropriate standards; and

(c) The applicant's proposed radiation detection instrumentation is adequate for conducting the diagnostic procedures specified in the appropriate standards.

6911. MANUFACTURE FOR MEDICAL DIAGNOSTIC USES.

6911.1 A specific license authorizing the distribution of radioactive material for use by physicians under the general license in § 6806 of chapter 68 of this title shall be issued only if the requirements of this section are met.

6911.2 The applicant for the license shall submit evidence that the radioactive material is to be manufactured, labeled, and packaged in accordance with the following:

(a) A new drug application which the Commissioner of Food and Drugs, of the Food and Drug Administration, has approved; or

(b) A license for a biologic product issued by the Secretary of Health and Human Services.

6911.3 A label or statement containing information as the Director may require shall be affixed to the container or shall appear in the leaflet or brochure that accompanies the package of radioactive material.

6912. RESEARCH AND DEVELOPMENT.

6912.1 A specific license for multiple quantities or types of radioactive material for use in research and development shall be issued if the requirements of this section are met.

6912.2 The applicant's staff shall have substantial experience in the use of a variety of radioisotopes for a variety of research and development uses.

6912.3 The applicant shall have established a radiation safety committee which will review and approve, in advance of purchase of radioisotopes, proposals for the radiological use.

6912.4 The committee required by § 6912.3 shall be composed of persons such as a radiological safety officer, a representative of the business office, and one (1) or more persons trained or experienced in the safe use of radioactive materials.

6912.5 The applicant shall appoint a radiological safety officer who will advise and assist on radiological safety problems.

6913. MEASURING, GAUGING, AND CONTROLLING DEVICES.

6913.1 A specific license to distribute certain devices of the types enumerated in § 6803 of chapter 68 of this title to persons generally licensed under that section shall be issued only if the requirements of this section are met.

6913.2 The applicant shall submit sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling, proposed uses, and potential hazards of the device to reasonably ensure the following:

(a) The radioactive material contained in the device will not be lost;

(b) No individual will receive a radiation exposure to a major portion of his or her body in excess of five-tenths (0.5) rem in a year under ordinary circumstances of use;

(c) The device can be safely operated by individuals not having training in radiological protection; and

(d) The radioactive material within the device will not be accessible to unauthorized individuals.

6913.3 In describing the label or labels and the label contents to be affixed to the device, the applicant shall separately indicate instructions and precautions that are necessary to assure safe operation of the device. The instructions and precautions shall be contained on labels bearing the statement, "REMOVAL OF THIS LABEL IS PROHIBITED."

6913.4 If the applicant desires that the device be tested for proper operation of the on-off

mechanism and indicator, if any, and for leakage of radioactive material, subsequent to the initial test required by §§ 6803.9 and 6803.10, at intervals longer than six (6) months, but not exceeding three (3) years, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the device or similar devices, and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device.

6913.5 In determining the acceptable interval for tests of leakage of radioactive material, the Director shall consider information on particulars which includes, but is not necessarily limited to, the following:

(a) Primary containment (source capsule);

(b) Protection of primary containment;

(c) Method of sealing containment;

(d) Containment construction materials;

(e) Form of contained radioactive material;

(f) Maximum temperature withstood during prototype tests;

(g) Maximum pressure withstood during prototype tests;

(h) Maximum quantity of contained radioactive material;

(i) Radiotoxicity of contained radioactive material; and

(j) Operating experience with identical devices or similarly designed and constructed devices.

6914. INDUSTRIAL RADIOGRAPHY.

6914.1 A specific license for use of sealed sources in industrial radiography (that is, the examination of the structure of materials by nondestructive methods utilizing sealed sources of radioactive material) shall be issued if the requirements of this section are met.

6914.2 The applicant shall have an adequate program for training radiographers and radiographers' assistants.

6914.3 The applicant shall submit to the Director a schedule or description of the program for training radiographers and radiographers' assistants which specifies the following:

(a) Initial training;

(b) Periodic training;

(c) On-the-job training;

(d) Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with regulations and licensing requirements, and the operating and emergency procedures of the applicant; and

(e) Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant.

6914.4 The applicant shall establish and submit to the Director operating and emergency procedures that comply with the standards issued by the Director.

6914.5 The applicant shall have an adequate internal inspection system, or another management control, to assure that license provisions, regulations, and the applicant's operating and emergency procedures are followed by each radiographer and each radiographer's assistant.

6914.6 The applicant shall submit to the Director a description of the applicant's overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program.

6914.7 The applicant who desires to conduct his or her own leak tests shall establish adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination, and shall submit to the Director a description of the procedures, including the following:

(a) Instrumentation to be used;

(b) Method of performing tests, such as the points on the equipment to be smeared and the method of taking a smear; and

(c) Pertinent experience of the person who will perform the test.

6915. PROCESSING FOR DISTRIBUTION.

6915.1 A specific license for multiple quantities or types of radioactive material for use in processing for distribution to authorized persons shall be issued only if the requirements of this section are met.

6915.2 The applicant's staff shall have substantial experience in the use of a variety of radioisotopes for processing and distribution.

6915.3 The applicant shall appoint a radiological safety officer who will advise and assist on radiological safety problems.

6916. USE OF EXEMPT CONCENTRATIONS IN PRODUCTS.

6916.1 A specific license for the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under § 6811.1 shall be issued only if the requirements of this section are met.

6916.2 The applicant shall submit the following information:

(a) A description of the product or material into which the radioactive material will be introduced;

(b) The intended use of the radioactive material and the product or material into which it is introduced;

(c) The method of introduction;

(d) The initial concentration of the radioactive material in the product or material;

(e) The control methods to ensure that no more than the specified concentration is introduced into the product or material;

(f) The estimated time interval between the introduction and the transfer of the product or material; and

(g) The radioactive material in the product or material at the time of transfer.

6916.3 The applicant shall provide reasonable assurance of the following:

(a) The concentrations of radioactive material at the time of transfer will not exceed the concentrations specified in standards issued by the Director;

(b) Reconcentration of the radioactive material in concentrations exceeding those in the standards issued by the Director is not likely;

(c) Use of lower concentrations is not feasible; and

(d) The product or material is not likely to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

6916.4 Each person licensed under this section shall file an annual report with the

Director that provides the following information:

(a) A description of the type and quantity of each product or material into which radioactive material has been introduced during the reporting period;

(b) The name and address of the person who owns or possesses the product or material into which radioactive material has been introduced;

(c) The type and quantity of radioactive material introduced into each product or material; and

(d) The initial concentrations of radioactive material in the product or material at the time of the transfer of the radioactive material by the licensee.

6916.5 The report required by § 6916.4 shall be submitted within thirty (30) days after the end of each calendar year in which the licensee introduces radioactive material into a product or material pursuant to a license granted under this section.

6917 - 6919. RESERVED.

6920. REGISTRATION OF RADIATION MACHINES.

6920.1 The owner or person having possession of any radiation machine, except those specifically exempted, shall register the machine with the Director.

6920.2 No person, in any advertisement, shall refer to the fact that a radiation machine is registered with the Director.

6920.3 No person shall state or imply that any activity conducted under his or her registration has been approved by the Director.

6920.4 The following machines and equipment are exempt from the radiation provisions of this title:

(a) Domestic television receivers manufactured after the effective date of these regulations and sold in the District that comply with the applicable federal requirements of 42 CFR 78.210, "Performance Standard for Television Receivers";

(b) Other electrical equipment that produces radiation incidental to its operation for other purposes; Providing, that the dose rate to the whole body at the point of nearest approach to the equipment when any external shielding is removed does not exceed five-tenths (0.5) rem per year. The production testing or factory servicing of the equipment shall not be exempt; and

(c) Radiation-producing machines while in transit or storage incident to that transit.

6921. RADIATION MACHINES AND REGISTRATION PROCEDURES.

6921.1 Registration shall be on forms furnished by the Director, and shall contain all information that the Director may require.

6921.2 The applicant shall designate an individual who will be responsible for radiation protection for the machine. This person shall:

(a) Be qualified by training and experience concerning all hazards and precautions involved in operating the machine for which he or she is responsible;

(b) Recommend a detailed program of radiation safety for effective compliance with the applicable requirements of the radiation provisions of this title;

(c) Give instructions concerning hazards and safety practices to individuals who may be exposed to radiation from the machine; and

(d) Make surveys and carry out other procedures as required by these regulations.

6921.3 When, in the opinion of the Director, the person designated to be responsible for radiation safety does not have qualifications sufficient to ensure safety of the machine for which the person is responsible, the Director may order the registrant to designate another individual who meets the qualifications.

6921.4 The Director shall issue a Notice of Registration to each applicant who has submitted the information required in § 6921.1.

6921.5 The Notice of Registration shall state the period of registration and shall be retained by the registrant for the stated period.

6922. RADIATION MACHINES: RENEWAL AND MODIFICATION OF REGISTRATION.

6922.1 The owner or person having possession of any registered radiation machine shall re-register the machine with the Director every two (2) years.

6922.2 The application for re-registration shall be submitted at least thirty (30) days prior to the expiration of the registrant's current Notice of Registration.

6922.3 When a registrant has filed an application not less than thirty (30) days prior to the expiration of his or her existing registration, and when the application has been filed in the proper form for renewal or amendment of the application, the existing registration shall be valid until a final decision has been made on the application by the Director.

6922.4 The registrant shall notify the Director within thirty (30) days of any change that renders the information furnished by him or her no longer accurate.

6922.5 A change in the ownership, possession, or address where a radiation machine is located shall terminate a registration.

6923. SUPPLIERS OF MEDICAL AND DENTAL X-RAY MACHINES.

6923.1 No person shall make, sell, lease, repair, transfer, lend, or install medical or dental x-ray equipment in the District unless authorized to do so by a license issued by the Director.

6923.2 Application to become a licensed supplier shall be filed on forms prescribed by the Director, and shall contain information as the Director may require.

6923.3 For the purposes of this section, a "licensed supplier" shall be a person who has been licensed by the Director to make, sell, lease, repair, lend, transfer, or install medical or dental x-ray equipment for use in the District.

6923.4 For the purposes of this section, "medical or dental x-ray equipment" shall mean any electronic device that produces x-rays by electrical means for the intentional exposure of humans.

6923.5 Any person licensed to supply medical or dental x-ray equipment in the District shall notify the Director on forms provided by the Director within fifteen (15) days following the sale, lease agreement, or decision to make available the equipment, or at least ten (10) days prior to the installation of the equipment, whichever occurs sooner.

6923.6 No medical or dental x-ray equipment shall be supplied in the District which, when properly placed in operation and properly used, does not meet the standards prescribed by the Director.

6923.7 Plans or blueprints of any medical or dental x-ray installation that is to receive x-ray equipment supplied by a licensed supplier shall be approved by the Director prior to the installation of the equipment.

6923.8 The Director may require information such as that required by § 6923.7 to be furnished to him or her as the Director deems necessary to determine compliance with the requirements of the radiation provisions of this title.

6923.9 Licenses to supply medical and dental x-ray equipment in the District may be terminated for any of the following reasons:

(a) Failure to provide advance notification to the Director of the installation of medical or dental x-ray equipment sold, leased, loaned, transferred, or installed in the District;

(b) When information on the application is determined to be incorrect, or no longer current, and the licensee fails to submit an amended application containing the corrected

information within thirty (30) days after the change takes place;

(c) Expiration of a temporary license; or

(d) Repeated failure to supply medical and dental x-ray equipment that meets the standards established by the Director.

6923.10 A temporary license may be granted by the Director for a specified period, not to exceed one (1) year, for those suppliers of x-ray equipment who wish to make a limited sale, lease, loan, transfer, or installation of medical or dental x-ray equipment, and who do not normally supply the equipment for profit.

6924. FEE SCHEDULE.

6924.1 Each owner or operator of an x-ray tube shall pay the following biennial registration fees:

(a) Dental X-Ray Tubes:

(i) Two hundred fifty dollars ($ 250.00) for the first tube; and

(ii) One hundred dollars ($ 100.00) for each additional tube.

(b) Medical X-Ray Tubes:

(i) Two hundred fifty dollars ($ 250.00) for the first tube; and

(ii) One hundred dollars ($ 100.00) for each additional tube.

6924.2 Each health physicist shall pay an annual registration fee of one hundred dollars ($ 100.00).

6924.3 Each x-ray supplier shall pay an annual registration fee of one hundred dollars ($ 100.00).

6924.4 Each radioactive material user shall pay an annual registration fee of five hundred dollars ($ 500.00).

6924.5 Each generator of low-level radioactive waste shall pay an annual registration fee of five thousand dollars ($ 5,000.00).

6924.6 All fees shall be due and payable upon filing an application for registration, or for renewal of registration, with the Department.

6924.7 The Director shall assess a late fee of fifty dollars ($ 50.00).

6924.8 A department, office, or agency of the District of Columbia Government shall not be required to pay a fee pursuant to this section, if the registration or services are required for a governmental purpose.

6924.9 All fees shall be paid by check or money order, made payable to the District of Columbia Treasurer.

6999. DEFINITIONS.

6999.1 The meanings ascribed to the definitions appearing in § 6799 of chapter 67 of this title shall apply to the terms in this chapter.